ORAL CONTRIBUTIONS

879 Novel Approaches in Coronary Stenting

Wednesday, April 02, 2003, 10:30 a.m.-Noon
McCormick Place, Vista S406 B

10:30 a.m.

879-1 Initial U.S. Experience With Membrane-Covered Stents in the Treatment of Saphenous Vein Graft Lesions: Roll-In Phase of the BARRICADE Trial

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Background: Percutaneous interventions in degenerated saphenous vein bypass grafts are associated with a high risk of periprocedural distal embolization resulting in myocardial infarction. We report the in-hospital outcomes of placement of a new polytetrafluoroethylene-covered stent in the first US experience with this device. **Methods:** As part of a prospective randomized multicenter trial (BARRICADE Trial), 88 patients were included in the roll-in phase with 104 lesions in SVGs. The use of distal protection devices was left to the discretion of the operator. In-hospital technical success, complications rate, and the incidence of MACE (death, Q-wave or non-Q-wave myocardial infarction (MI), and target vessel revascularization (TVR) were analyzed. **Results:** A total of 88 patients with a mean age of 67 years received 111 covered stents for 104 stenoses in vein grafts 10.2 ± 5.8 years after bypass surgery. Clinical characteristics included: diabetes (35%), hyperlipidemia (92%), hypertension (77%), and smoking (67%). Lesions characteristics included: reference diameter 3.7 ± 0.4 mm, lesion length 15.1 ± 5.9 mm, percent stenosis 84.2 ± 10.2%. Stent placement was successful in all patients. GP IIb/IIIa inhibitors were used in 66% and distal protection devices in 31% of cases. Complications and MACE rates are shown in the table below. **Conclusion:** The use of PTFE-covered stents appears to be safe and effective in treating high risk lesions in SVGs, with a relatively low risk of non-Q wave myocardial infarction.

In-hospital Complications and MACE

	Number	%
Death		
Cardiac	0	0
Non-cardiac(bleeding)	1	1.1
Q-wave MI	1	1.1
Non-Q-wave MI	6	6.8
TVR (abrupt closure)	1	1.1
Any event	8	9
Major vascular events	2	2.2

10:45 a.m.

879-2 Comparison of Saphenous Vein Graft Intervention With Bare Stents Plus Distal Protection Versus Membrane-Covered Stents Without Distal Protection: Data From SAFER and Roll-In Phase of BARRICADE Trials

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Background: Intervention in saphenous vein graft (SVG) lesions is associated with a high risk of cardiac events particularly non-Q wave MI. Distal protection reduces adverse cardiac events. However, there is limited data on the effectiveness of membrane-covered stents in treating SVG lesions.
Methods: We compared SVG intervention with bare stents plus distal protection in the Guard wire group of SAFER (Saphenous Vein Free of Emboli Randomized) trial with membrane-covered stents without distal protection in the roll-in phase of BARRICADE (Barrier Approach to Restenosis: Restrict Intima and Curtail Adverse Evens) trial. In SAFER, 406 patients were randomized to bare stents plus distal protection. The roll-in phase of BARRICADE trial included 59 patients without distal protection, who comprise the comparison group.
Results: Characteristics of patients in SAFER and BARRICADE were: age (68 +/- 10 vs 67 +/- 8), male (82% vs 75%), diabetes mellitus (33% vs 61%), and rest angina (39% vs 27%). All patients received aspirin and clopidogrel. IIb/IIIa inhibitors were given in 57% and 68% of patients respectively. Major adverse cardiac events at 30 days are shown (table).
Conclusions: These preliminary data suggest that a simple strategy of covered-stent placement for SVG lesions offer similar outcomes as bare stents combined with distal protection. A prospective trial comparing these two strategies is warranted.

Major Adverse cardiac Events at 30 Days.

Variable, n (%)	SAFER Trial N = 406	BARRICADE Trial N = 59	p value
Death	4 (1.0)	1 (1.7)	0.68
Q-wave MI	5 (1.2)	1 (1.7)	0.79
Non-Q wave MI (CK-MB > 3x ULN)	30 (7.4)	4 (6.8)	0.68
Repeat PCI	-	1 (1.7)	-
Composite endpoint	39 (9.6)	7 (11.9)	0.62

11:00 a.m.

879-3 Pilot Study With Oral Rapamycin in Patients Undergoing Stenting in Coronary Arteries: Buenos Aires Experience (ORAR Trial)

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Background: Rapamycin stent coated is associated with low restenosis. The use of oral rapamycin to prevent restenosis is unknown. **Methods:**From December 2001 to February 2002, 34 patients (pts) with 49 lesions were treated during one month with oral rapamycin. In different epicardial coronary vessels 49 stents were deployed. Rapamycin was given in a daily dose of 2 mg, starting with a loaded dosis of 6 mg. Rapamycin blood levels were measured in all pts during the third week of treatment. Cholesterol and triglycerides were evaluated before and one month after treatment. Independently of lipid values statins were given in all pts as well clopidrogrel during six months. Angiographic binary restenosis (> 50%), target vessel revascularization (TVR), target lesion revascularization, treatment compliance and major adverse events were analysed. Six months follow up angiogram was available in 98% of lesions (48/49). **Results:** Baseline characteristics showed diabetics in 32%, in stent restenosis in 32%, type B2 and C lesions in 49%, vessel size < 2.9 mm in 55% and with a lesion lenght of 11.9 ± 0.23 mm. One patient at day 21 discontinued the medication for skin rash and fever (3%). There were no other side effects in this cohort of pts. Follow up cholesterol and triglycerides showed no changes compared to basal levels. Angiographic restenosis was present in 23 % of lesions (11/48) with a TVR of 22.4% (11/49). Restenosis in the novo lesions was 16.2% (6/37) compared to 45.4% (5/11) in stent restenosis lesions, p=0.106. Restenosis in novo lesions with rapamycin blood level > 8 ng/ml was not founded (0/10) whereas was 22.2% (6/27) when the rapamycin blood level was < 8 ng/ml, p= 0.309. **Conclusions:** In this pilot observational study oral rapamycin taking during one month was safe and well tolerated. High rapamycin blood level appears to be associated with lower restenosis rate.

11:15 a.m.

879-4 Oral Sirolimus for Recalcitrant In-Stent Restenosis

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Background: Sirolimus coated stents are a promising new therapy for restenosis. At Scripps clinic we offered oral sirolimus to a select group of "no-option" patients at especially high risk for restenosis. These patients were followed for side effects and need for repeat revascularizations.
Methods: Patients were treated with a sirolimus loading dose of 6 mg after PTCA, followed by 2 mg/day for 4 weeks. A one month course of therapy was selected because in the RAVEL trial, efficacy was demonstrated using stents that delivered sirolimus over a 4-6 week duration. Serum electrolytes, lipid profile, renal panel, and complete blood cell count were measured at 1,3, and 5 weeks after drug initiation.
Results: Oral sirolimus was prescribed to 22 patients with 28 lesions at high risk for restenosis. Patient age was 57.1 +/- 10.6 years, 9(41%) were diabetics, and 20(91%) had previous brachytherapy failure. The mean number of previous restenoses per patient was 3.5 +/- 1.6. Of the 22 study patients, 11(50%) discontinued oral sirolimus early due to side effects or laboratory abnormalities. The mean treatment duration for patients that discontinued medication early was 14.5 +/- 6.5 days. Hypertriglceridemia and leukopenia were the most frequent adverse events, occurring in 3 patients each. All adverse drug effects were reversible after discontinuation. Follow up was obtained in 100% of patients at a mean of 10 +/- 2 months, ranging from 6.5-12 months. Target lesion revascularization occurred in 15 of 28 lesions (54%) and 13 of 22 patients (59%). There was no difference in TLR for patients receiving a complete 30 day course of sirolimus 8(62%) compared to patients who terminated treatment prematurely 5(38 %), p=NS. Clinically driven repeat cardiac catheterization was obtained in 15 (68%) patients; restensosis (>50% diameter stenosis at follow-up) was present in 13(87%).
Conclusion: Oral sirolimus does not appear to provide benefit to patients with recalcitrant restenosis. Adverse drug effects are frequent, underscoring the importance of local drug delivery to achieve high tissue concentrations without systemic adverse drug effects.